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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,889	01/29/2004	James H. Brauker	DEXCOM.006C1	7926

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,889	Applicant(s) BRAUKER ET AL.	
	Examiner Eric F. Winakur	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 and 40-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 22-39 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/2/05; 9/28/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species A in the reply filed on 29 October 2008 is acknowledged.
2. Claims 17 - 21, and 40 - 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 October 2008.

Claim Objections

3. Claim 4 is objected to because of the following informalities: it appears that the term "in" should be inserted before "at least". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 - 7, 13 - 16, 22 - 32, 37 - 39, and 45 - 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Antwerp (USPN 5,777,060 - cited by Applicant). Van Antwerp teaches a membrane and sensor covered with the membrane

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that includes a diisocyanate, a hydrophilic polymer, a siloxane polymer, and a chain extender (SUMMARY OF THE INVENTION, columns 3 - 4), where the membrane components and their properties are described in further detail in the Membrane Components section beginning at the bottom of column 5 - column 8. In particular, the hydrophilic polymer is porous to the analyte of interest, and the siloxane polymer is a silicone polymer. Implementation in a sensing arrangement is described in the Membrane-Coated Biosensors portion of column 9. With regard to certain of the claimed features, it is noted that these features (interconnected cavities of certain dimensions, etc) appear to relate to the claimed silicone domain. Thus, while Van Antwerp may not particularly detail these features, the disclosed silicone of the reference is considered to inherently possess these properties/features of the claimed silicone, since products of identical chemical composition cannot have mutually exclusive properties. With regard to claims 45 - 47, it is noted that while the claims are drawn to sensors, they are merely defined and limited by details of the membranes, all of which are taught by Van Antwerp.

6. Claims 1 - 8, 12, 14 - 16, 22 - 33, 37 - 39, and 45 - 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Gough (USPN 6,721,587 - cited by Applicant). Gough teaches a membrane and sensor arrangement (Figures 1 and 2; column 4, line 57 - column 5, line 27) for measuring glucose concentrations that includes a silicone region (column 6, lines 41 - 55) and a hydrophilic region (column 6, lines 56 - 67), made from various materials, and may additionally include a hydrophobic membrane (column 8, lines 24 - 35). With regard to certain of the claimed features, it is noted that these

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features (interconnected cavities of certain dimensions, etc) appear to relate to the claimed silicone domain. Thus, while Gough may not particularly detail these features, the disclosed silicone of the reference is considered to inherently possess these properties/features of the claimed silicone, since products of identical chemical composition cannot have mutually exclusive properties. With regard to claims 45 - 47, it is noted that while the claims are drawn to sensors, they are merely defined and limited by details of the membranes, all of which are taught by Gough.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 9 - 11 and 34 - 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough. Gough, as described above, teach all of the features of the invention, including examples of several material that may comprise the hydrophilic layer (column 6, lines 56 - 67), but do not particularly teach that the layer is made from polyurethane or polyurethane and polyvinylpyrrolidone. However, it would have been within the skill level of the art to determine appropriate materials for use as the layer, based upon the teaching of Gough and knowledge of material properties in possession of one of skill in the art at the time of the invention, since Gough teach the parameters for selecting appropriate materials for the layer, and it has generally been held to be

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within the skill level of the art to determine appropriate materials that meet such a set of requirements.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 2, 14, 26, 27, and 45 - 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 7,192,450 (cited by Applicant). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than those of the patent. Thus, any invention meeting the limitations of the claims of the patent would necessarily meet those of the instant application.

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11. Claims 1, 2, 14 - 16, 26, 27, and 45 - 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 6 and 15 - 17 of U.S. Patent No. 7,379,765. Although the conflicting claims are not identical, they are not patentably distinct from each other because one in possession of the invention of the patent would necessarily be in possession of the invention of the instant application.

12. Claims 1, 2, 14 - 16, 22 - 27, and 45 - 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13, 34, and 46 of copending Application No. 11/404,417. Although the conflicting claims are not identical, they are not patentably distinct from each other the claims of the instant application are broader than those of the co-pending application. Thus, any invention meeting the limitations of the claims of the co-pending application would necessarily meet those of the instant application. Further, claim 46 of the co-pending application is a sensor "configured to be wholly implanted". Thus, it would have been obvious to perform the method of claims 22 - 25 of the instant application to monitor analyte level with such an apparatus, since it has generally been held to be within the skill level of the art to perform the steps necessary to use a device for its intended purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1 - 5 and 26 - 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34, 39, and 45 of

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copending Application No. 11/763,215. Although the conflicting claims are not identical, they are not patentably distinct from each other the claims of the instant application are broader than those of the co-pending application. Thus, any invention meeting the limitations of the claims of the co-pending application would necessarily meet those of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clark, Jr., Wong et al., and Bennetto et al. teach sensors with membranes. Keogh et al., Kennedy et al., and Al-Lamee teach membrane structures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571/272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.